

REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 29-48) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recognized that the present invention provides hygienic protection for endoscopes, so that such instruments, which have become highly valuable medical diagnostic and procedure tools, can be readily re-used on a patient following recent use on a prior patient. Endoscopes, lacking proper protection against contamination, must generally be dismantled after each use and thoroughly cleaned, which is both time-consuming and quite expensive.

The present invention, as now claimed, provides hygienic protection for an endoscope, which includes a cover, which is closed at its distal end and which is transparent for optical information, at least on the front side thereof, with the cover able to be rolled thereon in a direction of the axis of the endoscope. One or more working channels for the endoscope extend in a parallel position in relation to the endoscope and terminate in an open manner on the distal end of the cover – the working channel being connected only to the distal end of the cover. The working channels are positioned between the outside of the endoscope and the inner side of the cover. There are one or more vacuum channels, having one or more openings, which terminate at the inside of the cover in a direction facing the endoscope, which are in addition to the working channels. As now explicitly claimed, the working channel(s) and the vacuum channel(s) are entirely separate from

one another, in that the one or more working channels are not useful for use as a vacuum channel, and vice versa, in contrast to the applied prior art.

More particularly, the vacuum channels terminate in an open manner within the envelope of the endoscope protection and can have additional side openings. These side openings advantageously terminate at the inside of the cover on the side of the cover (*i.e.*, an inner side or inner surface of the cover) facing in a direction of the endoscope. When a vacuum is applied to this channel, the air located between the cover and endoscope shaft is sucked out with the consequence being that the cover is drawn firmly onto the endoscope. The vacuum is then maintained during the examination. Thus, a fixed connection between the cover and endoscope, is produced advantageously and rapidly after the endoscope has been introduced into the cover, which is dimensioned somewhat larger in the interior diameter, preferably in the proximal part.

During application of the hygiene protection, one hand of the medical practitioner fixes the freely movable working channels and vacuum channels on the endoscope shaft, while the practitioner's other hand rolls on the cover above the channels. The combination of a protective cover, with its own working channels, extends outside of the endoscope with the protective cover and the working channels being connected to one another in the distal region of the cover in an airtight and germ-free manner. For attachment of the protection cover in accordance with the presently-claimed invention, the distal end of the cover is pushed onto the endoscope, so that the front face, which is transmissible for optical information, is correctly positioned, *i.e.*, positioned parallel to the distal end of the

endoscope. The optical contact between the endoscope and the transparent front face of the cover is preferably produced by means of a fluid, such as microscope immersion oil, which ideally has the same refractive index as the lens of the endoscope.

As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and hygienically effective protection apparatus and related method for an endoscope, having one or more separate working channels and vacuum channels, in which the openings of the vacuum channels terminate at the inside of the cover of the endoscope protection at an inner side of the cover facing in a direction toward the endoscope, either disclosed or suggested.

By the present amendments, Applicant has amended independent Claims 29, 47 and 48 to delete reference to “a patient” in defining the direction or placement of the one or more openings of the vacuum channel and now reciting that the vacuum channel opening(s) terminate –inside of said cover in a direction facing said endoscope--. Subject matter support for the newly-entered claim language exists in Applicant’s *Specification* at Page 4, lines 10-17, which states that:

“In addition to the working channels, in the endoscope protection according to the invention, at least one vacuum channel is provided. The vacuum channel terminates in an open manner within the envelope of the endoscope protection and can have additional side openings. These side openings terminate at the inside of the cover. *When a vacuum is applied to this channel, the air located between the cover and the endoscope shaft is sucked out, with the consequence that the cover is drawn firmly onto the endoscope.*” (Italics added)

As part of the third Office Action, the Examiner again rejected Claims 29-48 as being indefinite, pursuant to 35 U.S.C. §112, second paragraph, due to the recitation of “a

patient” in referencing a structural feature of the claimed invention. In light of Applicant’s present amendment, in which the direction of the openings of the vacuum channel are now defined with reference to the direction of the endoscope, and which amendment is submitted to be both well-supported and well-explained and understood by the foregoing language quoted from Applicant’s *Specification*, it is respectfully contended that the Examiner’s 35 U.S.C. §112, second paragraph, indefiniteness rejection has been overcome, or otherwise rendered moot, and should therefore now be withdrawn.

Turning now, in detail, to an analysis of the Examiner’s prior art rejections, in the third Office Action the Examiner has rejected independent Claims 29 and 47 as being obvious, pursuant to 35 U.S.C. §103(a), over Silverstein *et al.*, U.S. Patent No. 5,646,722, taken in view of Madni *et al.*, U.S. Patent No. 6,007,482. It is the Examiner’s contention that Silverstein *et al.* discloses an endoscope having a cover; the Examiner previously argued in the first Office Action, dated July 10, 2007, that Silverstein *et al.* did disclose a type of vacuum channel, however, it is unclear whether the Examiner still takes that position or is now merely making the more limited argument of stating that Silverstein *et al.* simply “fails to positively disclose a vacuum channel, having at least one opening, and terminating at said inside of said cover and at a side of said cover that is an inner side of said cover and faces away from patient.” Madni *et al.*, newly-cited by the Examiner, has been secondarily-applied for its contended teaching of a vacuum channel (29, 30) that has at least one opening and terminates in a manner as claimed by Applicant prior to the instant claim amendments. The Examiner has concluded in the third Office Action that it would have been obvious to have provided the endoscope protection/cover of Silverstein

et al. with the structure of the vacuum channels (29, 30) disclosed by Madni *et al.*, to yield that which is claimed by the instant Applicant.

In reply to the Examiner's obviousness rejection applying Silverstein *et al.*, taken in view of Madni *et al.*, Applicant respectfully contends that the primarily-applied citation of Silverstein *et al.* discloses an endoscope with a cover having a channel (36), which is apparently used for biopsy purposes. There would appear to be no teaching or suggestion of a "vacuum channel" by Silverstein *et al.*, and the Examiner's secondary application of Madni *et al.* would appear to suggest that Applicant and the Examiner are in substantial agreement on this point.

Madni *et al.* discloses an endoscope with a stretchable flexible sheath covering having two channels 29, 30. However, in sharp contrast to that which is claimed by Applicant, Madni *et al.* explains (at Col. 2, lines 32-34) that a portion of the bladder [27, 28] may be "selectively inflated by air pressure tubes **29, 30**." Consequently, it is contended that because channels 29, 30 are, in fact, pressurized air tubes that are necessarily incapable of being vacuum tubes, the teachings and suggestions of Madni *et al.* should, instead, be seen as teaching against the vacuum tubes utilized by Applicant as part of the presently claimed invention.

Considering Silverstein *et al.* in combination of Madni *et al.*, the primarily-applied citation of Silverstein *et al.* teaches a channel (36) that is used for biopsies, while the secondarily-applied reference of Madni *et al.* fails to disclose the use of a vacuum channel, but instead teaches the contrary use of two air-pressurized channels. Inasmuch

as neither of the applied citations discloses inclusion of a vacuum channel, it is respectfully submitted that the proposed combination of Silverstein *et al.*, taken in view of Madni *et al.* is incapable of rendering obvious the presently claimed invention.

In light of the foregoing, it is respectfully contended that the Examiner's 35 U.S.C. §103(a) obviousness rejection of independent Claims 29 and 49 (and various dependent claims), which applies Silverstein *et al.*, taken in view of Madni *et al.*, has been overcome and should now be appropriately withdrawn.

Separately, the Examiner has rejected independent method Claim 48 as being obvious, pursuant to 35 U.S.C. §103, over Silverstein *et al.*, taken in view of Madni *et al.*, and taken in further view of Crawford, U.S. Patent No. 5,944,654. In this obviousness rejection, the Examiner would appear to have applied Silverstein *et al.*, taken in view of Madni *et al.*, in the manner as applied against independent Claims 29 and 47. The added reference of Crawford has been applied for its contended teachings of providing depressions in an axial direction, as recited in one of the method steps of Claim 48.

In reply to the separate obviousness rejection applicable to independent method Claim 48, Applicant respectfully contends that the contrary teaching of Madni *et al.*, in which tubes, or channels, 29, 30, are used for inflation purposes of bladders (27, 28), renders inclusion of Madni *et al.* in combination with either Silverstein *et al.* or Crawford as inappropriate for the reasons detailed in Applicant's response to the obviousness rejection of independent Claims 29 and 47.

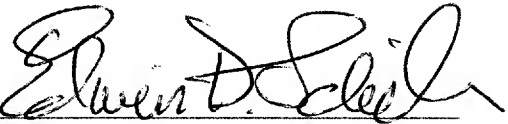
Accordingly, Applicant respectfully submits that the Examiner's 35 U.S.C. §103(a) obviousness rejection of independent method Claim 48 has now been overcome and should be withdrawn.

In view of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 29-48) recite a novel and hygienically effective protection apparatus and related method for an endoscope, wherein one or more separate working channels and vacuum channels are provided, in which the openings of the vacuum channels terminate at the inside of the cover in a direction facing the endoscope, which is patentably distinguishable over the prior art. Accordingly, with-

drawal of the outstanding rejections and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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Enc.: 1. Petition for Three-Month Extension of Time for Response; and,
2. EFT for \$555.00 (Three-Month Extension Fee).

The Commissioner for Patents is hereby authorized to charge the Deposit Account of Applicant's Attorney (*Account No. 19-0450*) for any fees or costs pertaining to the prosecution of the above-identified patent application, but which have not otherwise been provided for.